DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

WARNING LETTER NYK 2005-04

February 9, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ann M. Green, M.D.
South Bay OBGYN
320 Montauk Highway
West Islip, NY 11795

Re: MQSA Inspection ID 1798380011
FEI 1000521823

Dear Dr. Green:

On December 3, 2004, a representative of the New York State Department of Health, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA"), which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA at your facility. These violations were noted on the MQSA Facility Inspection Report that the inspector hand delivered along with the document "Important Information about Your MQSA Inspection" to [redacted] Office Manager, on December 6, 2004. The violations are again identified below with the corresponding citations from the Code of Federal Regulations (CFR):

Level 1: Phantom QC records were missing for at least 4 weeks for unit 2, [redacted] room Mammo Room [21 CFR 900.12(d)(2) and 21 CFR 900.12(e)(2)]

Level 1: Failed to produce documents verifying that the interpreting physician [redacted] met the initial requirement of holding a valid state license to practice medicine [21 CFR 900.12(a)(1)(i)(A)]

Level 1: Failed to produce documents verifying that the interpreting physician [redacted] met the initial requirement of holding a valid state license to practice medicine [21 CFR 900.12(a)(1)(i)(A)]

Level 1: Failed to produce documents verifying that the interpreting physician [redacted] met the initial requirement of holding a valid state license to practice medicine [21 CFR 900.12(a)(1)(i)(A)]

Level 1: Failed to produce documents verifying that the interpreting physician [redacted] met the initial requirement of holding a valid state license to practice medicine [21 CFR 900.12(a)(1)(i)(A)]

Level 1: Failed to produce documents verifying that the radiologic technologist [redacted] met the initial requirement of holding either a valid state license or a valid certificate from an FDA-approved body [21 CFR 900.12(a)(2)(i)(A) and (B)]

Level 1: Failed to produce documents verifying that the radiologic technologist [redacted] met the initial requirement of holding either a valid state license or a valid certificate from an FDA-approved body [21 CFR 900.12(a)(2)(i)(A) and (B)]

Level 1: Failed to produce documents verifying that the radiologic technologist [redacted] met the initial requirement of holding either a valid state license or a valid certificate from an FDA-approved body [21 CFR 900.12(a)(2)(i)(A) and (B)]

Level 2: Medical audit and outcome analysis was not done separately for each individual at site South Bay OBGYN (REPEAT) [21 CFR 900.12(f)(1)]

Level 2: The mammography processor equipment evaluation (by a medical physicist) for processor 0000000001, [redacted] room Darkroom, site South Bay OBGYN was not done [21 CFR 900.12(e)(10)]

Level 2: Processor QC records in the month of 01/2004 were missing for at least 10% but less than 30% of operating days, for processor 0000000001, [redacted] room Darkroom at site South Bay OBGYN5 [21 CFR 900.12(d)(2) and 21 CFR 900.12(e)(1)]

Level 2: Processor QC records were missing at least 2 but less than 5 consecutive days for processor 0000000001, [redacted] room Darkroom at site South Bay OBGYN [21 CFR 900.12(d)(2) and 21 CFR 900.12(e)(1)]

Level 2: Failed to produce documents verifying that the interpreting physician [redacted] (8 CME's in 36 months) met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months [21 CFR 900.12(a)(1)(ii)(B)]

Level 2: Failed to produce documents verifying that the interpreting physician [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months [21 CFR 900.12(a)(1)(ii)(A)]

Level 2: Failed to produce documents verifying that the interpreting physician [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months [21 CFR 900.12(a)(1)(ii)(A)]

Level 2: Failed to produce documents verifying that the interpreting physician [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months [21 CFR 900.12(a)(1)(ii)(A)]

Level 2: Failed to produce documents verifying that the interpreting physician [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months [21 CFR 900.12(a)(1)(ii)(A)]

Level 2: Failed to produce documents verifying that the interpreting physician [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months [21 CFR 900.12(a)(1)(ii)(A)]

Level 2: Failed to produce documents verifying that the radiologic technologist [redacted] (8 CEU's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months [21 CFR 900.12(a)(2)(iii)(A) and (C)]

Level 2: Failed to produce documents verifying that the radiologic technologist [redacted]10 CEU's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months [21 CFR 900.12(a)(2)(iii)(A) and (C)]

Level 2: Failed to produce documents verifying that the radiologic technologist [redacted](8 CEU's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months [21 CFR 900.12(a)(2)(iii)(A) and (C)]

Level 2: Failed to produce documents verifying that the medical physicist [redacted] (13 CME's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months [21 CFR 900.12(a)(3)(iii)]

Level 2: Medical audit and outcome analysis was not done for the facility as a whole at site South Bay OBGYN [21 CFR 900.12(f)(1)]

Level 2: Medical audit and outcome analysis was not performed annually at site South Bay OBGYN [21 CFR 900.12(f)(2)]

Level 2: There is no designated audit (reviewing) interpreting physician for site South Bay OBGYN [21 CFR 900.12(f)(3)]

You have failed to respond to the MQSA Facility Inspection Report as requested in the document "Important Information about your MQSA Inspection" and also failed to respond to an additional communication by our office in the form of a letter dated January 11, 2005.

Because the continued failure to resolve these violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review;
- placing your facility under a Directed Plan of Correction;
- charging your facility for the cost of on-site monitoring;
- seeking civil money penalties up to $11,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards;
- seeking to suspend or revoke your facility's FDA certificate; and
- *seeking a court injunction against your facility.*

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

You should respond in writing to FDA within fifteen (15) working days from the date you received this letter. Your response should address the findings listed above and include:

1. the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps; and

3. sample records that demonstrate proper record keeping procedures.

Please submit your response to this letter to:

Patricia A. Clark, Compliance Officer
U.S. Food and Drug Administration
300 Pearl Street, Suite 100
Buffalo, New York 14202

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection of your facility and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

If you have additional or more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Patricia A. Clark, Compliance Officer at 716-551-4461, ext 3168.

Sincerely yours,

Jerome G. Woyshner
District Director

cc: Gerald O'Connor
Associate Radiological Health Specialist
New York State Department of Health
Center for Environmental Health
Bureau of Environmental Radiation Protection
547 River Street
Troy, New York 12180

cc: Priscilla F. Butler, M.S., FAAPM
Director, Breast Imaging Accreditation Programs,
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091